REMARKS/ARGUMENTS

Applicants thank the Examiner for the thorough review of the application.

Claims 1-5 and 8 are amended. Claim 10 is cancelled. Claims 1-5, 7-9, and 13 are pending in the application.

Claim 1-5 now recite a hydrate and/or a hydrate of a salt. Support for the amendment is found for example at page 5, lines 10-13, of Applicants' specification.

Support for the amendment of claim 8 is found for example in claim 10 as originally filed.

The amendment is made without prejudice or disclaimer. Applicants reserve the right to pursue the cancelled subject matter in continuation or divisional applications.

No new matter has been added by way of this amendment, the entry of which is respectfully requested.

Claim Objections

Claims 1-5 stand objected to because of informalities.

The claims have been amended to incorporate the Examiner's suggestions. It is respectfully submitted that the objections are moot and their withdrawal is respectfully requested.

Claim Rejections – 35 USC § 112, 1st paragraph

Claims 8-10 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement.

The Examiner alleges that the claim(s) contain subject matter which was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope that these claims. The Examiner alleges that the prophylaxis or treatment of "impairments of perception, concentration, learning and/or memory" also known as dementia, is not enabled.

Applicants respectfully disagree and traverse the rejection.

However, in order to expedite the examination of the instant application, claim 8 is amended and claim 10 is cancelled without prejudice or disclaimer. Claim 8 is now drawn to a method for improving impairments of learning and/or memory comprising administering to a human or animal an effective amount of a compound of claim 1.

Applicants respectfully submit that Applicants' specification provides sufficient guidance for the claimed invention. For example, at pages 17-22, Applicants specification provides several assays or tests to make and use the claimed invention. An assay for PDE inhibition is disclosed at pages 17-19 of Applicants' specification. An assay for intracellular neuronal cGMP concentration in cell cultures is disclosed at pages 19-20 of Applicants' specification. An assay for long term potentiation is disclosed at pages 20-21 of Applicants' specification, and a social recogition test is disclosed at pages 21-22 of Applicants' specification.

Applicants therefore respectfully submit that Applicants' specification provides sufficient guidance to enable one skilled in the art to make and/or use the claimed invention without undue experimentation. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-5, 7 and 13 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound, medicament or the salt thereof, allegedly does not reasonably provide enablement for the solvates and/or the solvates of the salts thereof.

The Examiner alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope that these claims.

Applicants respectfully disagree and traverse the rejection.

However, in order to expedite the examination of the instant application, claim 1-5 are amended without prejudice or disclaimer. Claims 1-5 are now drawn to a claimed compound, a salt, a hydrate and/or a hydrate of a salt thereof.

Applicants respectfully submit that Applicants' specification provides sufficient guidance for the claimed invention. For example, Applicants' specification provides guidance for the claimed invention at page 5, lines 10-13.

The Examiner cites *Vippagunta et al.* in the rejection. The section of the reference cited by the Examiner refers to the prediction of the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound. It is however the prediction of both that appears to be qualified as complex and difficult in the reference, rather than the formation of solvates or hydrates itself. Accordingly, it is respectfully submitted that *Vippagunta* does not support the Examiner's arguments.

On the contrary, other sections of *Vippagunta* support the conclusion that there is a reasonable expectation of success for the formation of solvates and hydrates. For example, *Vippagunta* on page 15, top of first column, states that

> It has been established that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. (Emphasis added.)

Likewise, the abstract of *Vippagunta* starts with the statement that

> Many drugs exist in the crystalline solid state due to reasons of stability and ease of handling … Crystalline solids can exist in the form of polymorphs, solvates or hydrates. (Emphasis added.)

Also on page 4, first paragraph, *Vippagunta* states that

> Most organic and inorganic compounds of pharmaceutical relevance can exist in one or more crystalline forms. …
>
> The common crystalline forms found for a given drug substance are polymorphs and solvates. (Emphasis added.)

Moreover, *Vippagunta* throughout the reference teaches various solvates, hydrates, structural aspects thereof, examples thereof, including preparation techniques, and methods/techniques for the characterization thereof (see, e.g., pages 15-18).

Therefore, *Vippagunta*, rather than supporting a lack of predictability, supports the opposite, i.e., that there is a reasonable expectation of success for the claimed invention.

The Examiner further argues that Applicants has provided no working examples of any solvates or solvates of acceptable salts mentioned above in the present application.

Applicants respectfully submit that an applicants' disclosure is not required to present examples or *in vivo* or *in vitro* test results to establish enablement. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. §112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). The inventors in the instant disclosure have described how to make and use the invention in terms which correspond in scope to those in the claims. The Office action fails to provide sufficient evidence or objective reasoning to raise doubt about the truth or accuracy of the inventors' statements on this points. The burden of proof rests on the Patent and Trademark Office to show non-enablement and the evidence of record, as discussed above, fails to meet the burden of proof.

Applicants therefore respectfully submit that Applicants' specification provides sufficient guidance to enable one skilled in the art to make and/or use the claimed invention without undue experimentation. Accordingly, withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 8-10 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-3 of U.S. Patent Publication Application No. 2006/010022.

The instant appplication is the earlier filed application and since both applications are still are pending, Applicants respectfully request that the rejection be deferred until the instant application has been found allowable or until Patent Publication Application No. 2006/010022 is patented (see MPEP 804 I.B.1.).

In view of the above, Applicants respectfully submit that all objections and rejections have been addressed and that the application is now in condition for allowance. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

Respectfully submitted,

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